COMMITTEE REPORT

MADAM PRESIDENT:

The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1382, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, delete lines 30 through 39, begin a new line block indented and insert:

"(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement

from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 3, line 5, delete "may not exclude" and insert "**must include**".

Page 3, line 9, delete "may not be excluded" and insert "**must be included**".

Page 3, line 23, delete "Under a patient informed consent document, no party is" and insert "**This section does not create a cause of action against an insurer or health maintenance organization for any harm to an individual resulting from a clinical trial.**".

Page 3, delete lines 24 through 28.

Page 3, line 29, delete "IC 12-15-5-9" and insert "IC 12-15-5-9.2".

Page 3, line 31, delete "Sec. 9." and insert "**Sec. 9.2.**".

Page 4, line 41, delete "may not exclude" and insert "**must include**".

Page 5, line 3, delete "may not be excluded" and insert "**must be included**".

Page 5, delete lines 21 through 25.

Page 7, line 30, delete "may not" and insert "**must include**".

Page 7, line 31, delete "exclude".

Page 7, line 35, delete "may not be excluded" and insert "**must be included**".

Page 8, line 7, delete "(a) Under a patient informed consent document, no party" and insert "**This chapter does not create a cause of action against an insurer for any harm to an individual resulting from a clinical trial.**".

Page 8, delete lines 8 through 12.

Page 8, line 13, delete "IC 27-13-7-20" and insert "IC 27-13-7-20.2".

Page 8, line 15, delete "20." and insert "**20.2.**".

Page 9, delete lines 15 through 24, begin a new line block indented and insert:

"**(1) The health care service, item, or investigational drug that is the subject of the clinical trial.**

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 9, line 26, delete "may not exclude" and insert "**must include**".

Page 9, line 30, delete "may not be excluded" and insert "**must be included**".

Page 10, line 4, delete "Under a patient informed consent document, no party is" and insert "**This section does not create a cause of action against a health maintenance organization for any harm to an individual resulting from a clinical trial.**".

Page 10, delete lines 5 through 10.

Page 10, line 15, delete "IC 12-15-5-9," and insert "**IC 12-15-5-9.2,**".

Page 10, line 21, delete "IC 27-13-7-20," and insert "**IC 27-13-7-20.2,**".

(Reference is to HB 1382 as reprinted February 13, 2009.)

and when so amended that said bill do pass .

Committee Vote: Yeas 7, Nays 0.

_____

Senator Miller, Chairperson